K102715

DEC 17 2010

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Nonin Medical, Inc.

Contact Person: Lori M. Mitchell RN, BSN
Clinical/Regulatory Specialist
Nonin Medical, Inc.
13700 1st Ave. North
Plymouth, MN 55441-5443

Date Prepared: September 17, 2010

Trade Name: Model 7600 Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA)

Classification Name: and Number: Class II, 21 CFR 870.2700

Product Code: MUD

Predicate Device(s): Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) are substantially equivalent to the Nonin Medical, Model 7600 Regional Oximeter System (K090807), CAS Medical, Fore-Sight® Cerebral Oximeter MC-2000 (K091452), Somanetics Corporation, INVOS® Model 5100B Adult/Pediatric Cerebral Oximeter (K051274).

Device Description: Nonin's® Model 7600 4-Channel Regional Oximeter System with Equanox™ Technology and Bluetooth® Wireless Technology and compatible sensors (8004CA, 8000CA) continuously monitor and record the mixed arterial/venous blood oxygen levels through non-invasive near-infrared spectroscopy sensors.

The system is comprised of three subsystems; sensor, patient oximetry device (pod) and 4-channel display unit.

The sensor allows light absorption measurements at various wavelengths in the near-infrared spectrum (approximately 700 to 900 nanometers). The sensor is approximately 1.5 by 3 inches.

The sensors plug into the patient oximetry device (pod) which controls the light emitted from the sensor LEDs and measures the light returning to the sensor photodiodes. From these measurements, the pod determines specific absorption values and calculates the mixed arterial/venous oxygen saturation values. The pods then communicate the regional oxygen saturation readings and other data to the display unit.

The 4-channel display unit displays absolute real-time regional hemoglobin oxygen saturation (rSO_2) numeric data and trend lines. It is a battery-backed, mains powered device equipped with audio and visual alarm indicators. Real-time data and playback output is accomplished through a Bluetooth transceiver module.

Intended Use:

Model 7600 4-Channel Regional Oximeter System:

Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (>40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8004CA Regional Sensor:

The 8004CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8004CA sensor without baseline re-establishment. It is intended for use in environments including the operating

room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8000CA Regional Sensor:

The 8000CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8000CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Functional and Safety Testing:

Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) have successfully undergone extensive performance, electromagnetic, safety, clinical, environmental, and software testing to ensure that it has appropriate functional features and is substantially equivalent to the predicate devices.

Conclusion:

Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) are substantially equivalent to the Nonin Medical, Model 7600 Regional Oximeter System (K090807), CAS Medical, Fore-Sight® Cerebral Oximeter MC-2000 (K091452), Somanetics Corporation, INVOS® Model 5100B Adult/Pediatric Cerebral Oximeter (K051274).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lori M. Mitchell
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Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minneapolis 55441-5443

DEC 17 2010

Re: K102715
Trade/Device Name: Nonin Medical, Inc. Model 7600 4-Channel Regional Oximeter With Equanox™ Technology and Bluetooth® Wireless Technology and Compatible Regional Sensors (Models 8004CA and 80000CA)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: September 17, 2010
Received: September 20, 2010

Dear Ms. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

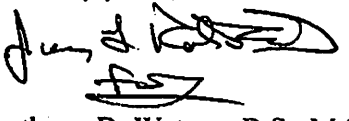
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K102715

Device Name:

Nonin Medical, Inc. Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA)

Indications for Use:

Model 7600 Regional Oximeter System:

Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8004CA Regional Sensor:

The 8004CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8004CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8000CA Regional Oximeter Sensor:

The 8000CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8000CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102715

Deputy Division Director
1/10/2011